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Certificate of Mailing (37 C.F.R. §1.8)

I hereby certify that this paper, and the papers and/or fees referred to herein as transmitted, submitted or enclosed, are being deposited on the date of deposit shown below with the U.S. Postal Service with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20232.

Signature: \_\_\_\_\_

*Kim R. Jessum*

Date of Deposit: \_\_\_\_\_

*July 17, 2002*

Name: \_\_\_\_\_

Kim R. Jessum

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Maximilian Polyak  
Ben O'Mar Arrington

Application No.: 09/976,804

Filed: October 12, 2001

For: COLD STORAGE SOLUTION FOR  
ORGAN AND BIOLOGICAL TISSUE  
PRESERVATION

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Group Art Unit: 1623

Examiner: Unknown

**SUPPLEMENTAL INFORMATION**  
**DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the following documents. This Supplemental Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits.

Copies of the documents, or abstracts thereof, set forth below and in the attached PTO-1449A form are provided. Applicants respectfully request that the Examiner consider the listed documents and evidence that consideration of relevant portions thereof by making appropriate notations on the attached form.

The relevance of CN-1178070 is that it discloses a solution for preserving organs for transplantation. The relevance of JP-06-305901 is that it discloses a perfusate used to preserve transplantation organs under room temperature.

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U.S. Patents

<u>Patent No.</u>	<u>Inventor</u>	<u>Issue Date</u>
5,919,703	Mullen, et al.	07/06/99
5,693,462	Raymond	12/02/97
5,552,267	Stern, et al.	09/03/96
5,498,427	Menasche	03/12/96
5,407,793	Del Nido et al.	04/18/95
5,370,989	Koga, et al.	12/06/94
5,200,398	Strasberg, et al.	04/06/93
5,080,886	Mickle, et al.	01/14/92
4,994,367	Bode, et al.	02/19/91

Foreign Patents

<u>Publication No.</u>	<u>Publication Date</u>	<u>Country</u>
1178070	04/08/98	CN
96/03139	02/08/96	WO
06305901	11/01/94	JP

Other Publications

POLYAK, M.M.R., et al., Calcium Ion Concentration of Machine Perfusate Predicts Early Graft Function in Expanded Criteria Donor Kidneys, 1999, Transplant International, 12(5):378-382.

POLYAK, M., et al., Pulsatile Preservation Characteristics Predict Early Graft Function in Extended Criteria Donor Kidneys, 1997, Transplantation Proceedings 29:3582-3583.

POLYAK, M., et al., The Influence of Pulsatile Preservation on Renal Transplantation in the 1990s, 2000, Transplantation 69:249-258.

POLYAK, M., et al., Glutathione Supplementation During Cold Ischemia Does Not Confer Early Functional Advantage in Renal Transplantation, 1999, Transplantation, 70(1):202-205.

POLYAK, M., et al., Supplemental Reduced Glutathione During Cold Ischemia Does Not Improve Early Renal Allograft Function, 2000, Transplantation Proceedings, 32:32-34.

POLYAK, M., et al., Donor Treatment with Phentolamine Mesylate Improves Machine Preservation Dynamics and Early Renal Allograft Function, 1999, Transplantation, 69(1):184-186.

POLYAK, M., et al., The State of Renal Preservation for Transplantation in New York, 1999, Transplantation Proceedings, 31:2091-2093.

POLYAK, M., et al., Prostaglandin E1 Influences Pulsatile Preservation Characteristics and Early Graft Function in Expanded Criteria Donor Kidneys, 1999, Journal of Surgical Research, 85:17-25.

POLYAK, M., et al., Prostaglandin E1 Improves Pulsatile Preservation Characteristics and Early Graft Function in Expanded Criteria Donor Kidneys, 1998, ASAIO Journal 44:M610-M612.

POLYAK, M., et al., Novel Preservation Solution Improves Early Function in the Cold Stored and Machine Preserved Kidney, 2001, American Journal Of Transplantation 1(1), Abstract #1330.

SUN, S.C., et al., Improved Recovery of Heart Transplants by Combined Use of Oxygen-Derived Free Radical Scavenges and Energy Enhancement, Journal of Thoracic and Cardiovascular Surgery, 1992, Issn 0022-5223, Volume 104, pages 830-837.

LE GAL Y.M., et al., Heart-Lung Protection from Ischemic Injury during 8 Hour Hypothermic Preservation, Acta Bio-Medica de L'Ateneo Parmense: Organo Della Societa di Medicina e Scienze Naturali di Parma, Italy, 1994, Issn 0392-4203, Volume 65, pages 181-198.

HIROMI, WADA, et al., Effective 30-hour Preservation of Canine Lungs with Modified ET-Kyoto Solution, Annals of Thoracic Surgery, 1996, Issn 0003-4975, Volume 61, pages 1099-1105.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies the document as "prior art" against any claim in the application and Applicants determine that the cited document does not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such document.

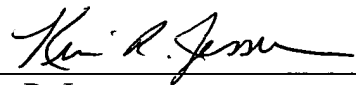
Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed document, should the document be applied against the claims of the present application.

**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

**MORGAN, LEWIS & BOCKIUS LLP**

Dated: July 17, 2002

By:   
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Reg. No. 43,694

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Substitute for form 1449A/BTC		<b>Complete if Known</b>		<b>RECEIVED</b> JUL 25 2002 TECH CENTER 1600/2900
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				
Sheet	1	Application Number	09/976,804	
		Filing Date	October 12, 2001	
		First Named Inventor	Polyak, et al.	
		Group Art Unit	1623	
		Examiner Name	Unassigned	
		Attorney Docket Number	053137-5001-01	

U.S. PATENT DOCUMENTS						
Exr Initials	U.S. Patent Document		Name of Inventor or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
	Number	Kind Code (if known)				
	5,919,703		Mullen, et al.	07/06/99		
	5,693,462		Raymond	12/02/97		
	5,552,267		Stern, et al.	09/03/96		
	5,498,427		Menasche	03/12/96		
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FOREIGN PATENT DOCUMENTS						
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	Country Code	Number	Kind Code (if known)			
	CN	1178070	A	Liu, et al.	04/08/98	
	WO	96/03139	A1	Stamler	02/08/96	
	JP	06305901		Kawamura	11/01/94	
OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS						
Exr Initials	Include Name of Author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published					T <sub>1</sub>
✓	POLYAK, M.M.R., et al., Calcium Ion Concentration of Machine Perfusate Predicts Early Graft Function in Expanded Criteria Donor Kidneys, 1999, Transplant International, 12(5):378-382.					
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Sheet 2		Attorney Docket Number	053137-5001-01

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Exr Initials	Include Name of Author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sub>1</sub>
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✓	SUN, S.C., et al., Improved Recovery of Heart Transplants by Combined Use of Oxygen-Derived Free Radical Scavenges and Energy Enhancement, Journal of Thoracic and Cardiovascular Surgery, 1992, Issn 0022-5223, Volume 104, pages 830-837.	
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Examiner Signature	1-PH/1636736.3	Date Considered	
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